DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

Aug 1, 2000

Mrs. Cathy Morris
President, AHFSA
c/o New Jersey Department of Health
and Senior Services
P.O. Box 367
Trenton, New Jersey 08625

Dear Mrs. Morris:

We have received several comments from health care providers, state Survey and Certification Agencies, and the regional offices regarding a difference between the Food and Drug Administration (FDA) and the Health Care Financing Administration (HCFA) concerning what constitutes a physical restraint, especially as it relates to side rail use. This letter was developed by the FDA and HCFA as a product of the Hospital Bed Safety Project. The intent of the letter is to clarify the difference in interpretation of restraints between the two agencies. We would appreciate your assistance in communicating this clarification by distributing this letter to the states.

Used improperly, restraints, including side rails, can pose a serious health and safety risk to nursing-home residents. Under HCFA's requirements for nursing homes that receive Medicare and Medicaid funding, restraints should only be used when other, less severe alternatives fail to address a resident's medical needs, and the benefits outweigh the potential risks. In such cases, the nursing home must ensure that any restraints are used safely and properly.

HCFA and the FDA each define physical restraint in accordance with its own statutory authorities. These differences in definition do not compromise the ability of the agencies to enforce their own regulatory requirements. Medical device manufacturers must comply with FDA requirements. Medicare and Medicaid providers must comply with HCFA requirements in order to become, or remain certified.

The FDA defines "protective restraint" at 21 CFR Section 880.6760 as:

> "a device, including but not limited to a wristlet, anklet, vest, mitt, straight jacket, body/limb holder, or other type of strap that is intended for medical purposes and that limits the patient's movements to the extent necessary for treatment, examination, or protection of the patient or others"

The FDA definition of a protective restraint device refers to a device attached to the individual, such as something a resident or patient would wear. It does not include any device that is adjacent to an individual, such as a side rail, a tray table, or a geri-chair. Further, the FDA definition is based on the intended use as it appears in the label, labeling, and/or promotional material for the device. The FDA regulates products as medical devices which fall within the definition of a device as that term is defined under section 201 (h) of the Federal Food, Drug and Cosmetic Act. The FDA product clearance process and regulations for manufacturers should help ensure that, if clinically appropriate, such restraints will be applied safely. Many products that restrict freedom of movement do not fall under the FDA's jurisdiction (e.g., geri-chairs). Even if these were medical devices, the FDA's position is that it would be inappropriate to identify all such devices as restraints, when that is not the intended use of the device as reported by the manufacturer. However, if a manufacturer intends or promotes a device to be used as a restraint, or is aware that the device is used as a restraint, that manufacturer must comply with the FDA's labeling requirements to relabel the device for its new intended use as required by 21 CFR Section 801.4. The FDA encourages consumers or health care workers to report instances where manufacturers of such products are not complying with the requirement for protective restraints. The FDA may be reached by contacting a local FDA Disrict Office, faxing information to the FDA's General Hospital Devices Branch at (301) 594-4638, or via the Internet at www.fda.gov.

HCFA's requirements pertaining to the use of restraints in nursing homes are at 42 CFR Section 483.13 (a). HCFA defines physical restraints under Interpretive Guidance in the State Operations Manual as:

> "any manual method or physical or mechanical device, material, or equipment attached *or adjacent to* the individual's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body." [Emphasis added]

The definition of restraints applicable to hospitals at 42 CFR 482.13 (e) is very similar. HCFA's definition of restraints in both nursing homes and hospitals is a functional definition, based on the effect on the individual. Accredited hospitals are expected to be in compliance with HCFA's restraint requirements. Under HCFA's definition, a restraint could include anything from a vest restraint, to a geri-chair or tray table, to a side rail, or even a sheet, if it has the effect of restricting freedom of movement or normal access to one's body.

A product or device that is not considered a restraint under the FDA definition may be considered a restraint under HCFA's definition, depending on the effect of the device on the individual. For example, the FDA would not consider a sheet to be a restraint, but if a sheet is tied around an individual so that it restricts their freedom of movement, then it is a restraint according to HCFA's definition. The FDA would not consider a side rail a restraint, however, any time side rail use (whether partial; full; one or two; or a side rail on one side of the bed with the other side of the bed against the wall) has the effect of preventing an individual from voluntarily getting out of bed, it is a restraint according to HCFA's definition. The FDA would also not consider geri-chairs, or tray tables a restraint, but if the effect is that the individual is prevented from rising, then it is a restraint according to HCFA's definition.

HCFA regulations require that restraints are used only when necessary to treat a resident's medical symptoms. The FDA supports HCFA's restraint reduction initiatives.

Sincerely,

/s/

Timothy M. Westmoreland, Director
Center for Medicaid and State Operations
Health Care Financing Administration

/s/

David W. Feigal, MD, MMPH, Director
Center for Devices and Radiological Health
Food and Drug Administration